PPTA
Plasma Protein Therapeutics Association

May 13, 2002
Reference No. FDAA02012

VIA HAND DELIVERY

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: Draft Guidance entitled, "Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Products Recipients and Their Intimate Contacts (February 2002)," Docket No. 99D-5347

Dear Sir or Madam:

PPTA is pleased to provide these comments on the Food and Drug Administration's (FDA's) draft guidance entitled, "Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Products Recipients and Their Intimate Contacts (February 2002)" (hereinafter "Draft Guidance"). The Plasma Protein Therapeutics Association (PPTA) is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat a complex of diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, and albumin which is used in emergency room settings to treat individuals with shock, trauma, and burns among other things. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies for the people who depend on them.

PPTA member companies would like to express concern about the impact the Draft Guidance could have on Source Plasma collections and the availability of plasma-derived therapies. The perceived theoretical benefits of the Draft Guidance are greatly outweighed by these likely negative consequences. In particular, PPTA recommends that additional donor questions are not warranted as the current procedures provide adequate safeguards for deferring those donors that may pose a theoretical risk.

PPTA understands the Agency's position that xenotransplantation recipients should not be permitted to donate blood or plasma because of a theoretical risk to recipients.

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However, PPTA also believes that the current donor screening questions are adequate to provide for effective deferral of xenotransplantation recipients.

Plasma centers, like whole blood centers, routinely ask donors if they are under a doctor's care, taking any medication, had any recent surgeries, or have ever received a tissue or organ transplant. The donor screening questions currently in place, in addition to the physical exam performed, are designed to result in the deferral of xenotransplant recipients.

Moreover, providing additional questions, as recommended in the Draft Guidance, will likely cause confusion and will not be as effective as existing questions in deferring xenotransplant recipients. In 2000, FDA advocated the organization of a task force to re-design the Uniform Donor History Questionnaire (UDHQ) to improve donor comprehension of the questions. PPTA has participated on this Task Force lead by the American Association of Blood Banks (AABB). Representatives from America's Blood Centers, American Red Cross, liaisons from the Centers for Disease Control and Prevention (CDC), and FDA have also participated in this industry-wide effort. The Task Force reviewed the xenotransplant questions proposed in the February 2001 Draft Guidance entitled, "Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans." As part of the Task Force effort, a focus group study was performed to determine donor comprehension of the questions specific to the topic of xenotransplantation. The study showed that most donors were not familiar with "xenotransplantation", and did not understand the questions.

Furthermore, FDA already has safeguards in place to ensure that xenotransplantation recipients do not become blood or plasma donors. In the United States all xenotransplantation products and procedures are experimental and must be performed in accordance with FDA-approved research protocols. As a part of these protocols, investigators are required to counsel recipients that both recipients and their intimate contacts should not donate blood, plasma, tissue or organs.

It is likely that the questions proposed in the current Draft Guidance would confuse prospective donors without providing any incremental gain in safety. Requiring the institutions and programs that initiate and support xenotransplantation to counsel transplant recipients would be a more effective means to notify the individuals at risk that they must not donate plasma, rather than posing these questions to all blood and plasma donors. Given the current need for attracting new donors and increasing donation frequency, PPTA recommends against the addition of the proposed questions in the Draft Guidance. This recommendation is based on the likelihood that the current UDHQ questions and the counseling performed by clinical investigators participating in research protocols regulated by FDA, will exclude those donors that may pose a theoretical risk.

PPTA appreciates the opportunity to comment on this Draft Guidance. Should you have any questions regarding these comments or would like additional information, please contact PPTA. Thank you for your consideration.

Respectfully submitted,

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